

201-15419



rdenison@environmentaldefense.org

06/29/2004 09:50 PM

To: NCIC OPPT@EPA, ChemRTK HPV@EPA, Rtk Chem@EPA, NCIC HPV@EPA, Karen Boswell/DC/USEPA/US@EPA, Ronald.Joiner@GEP.GE.COM
cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org
Subject: Environmental Defense comments on 1,3-Isobenzofurandione, 5,5'-[(methylethylidene)bis(4,1-phenyleneoxy)]bis- (CAS# 38103-06-9)

(Submitted via Internet 6/29/04 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and Ronald.Joiner@GEP.GE.COM)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for 1,3-Isobenzofurandione, 5,5'-[(methylethylidene)bis(4,1-phenyleneoxy)]bis- (CAS# 38103-06-9).

The General Electric Company, in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted robust summaries and a very brief test plan describing available data and proposed testing to address SIDS elements required for 1,3-Isobenzofurandione, 5,5'-[(methylethylidene)bis(4,1-phenyleneoxy)]bis-, also known as bisphenol A dianhydride. Our review indicates that very little information is provided by this submission. Bisphenol A dianhydride is said to be used as a reactive intermediate in the synthesis of high molecular weight polyetherimide polymers. No other background information is provided. (Given that more than one million pounds of this chemical are produced annually, we think General Electric Company could have usefully provided some of what it knows regarding its production, transport, occupational exposure, etc.)

It appears that bisphenol A dianhydride has been the subject of very little toxicological or any other type of study. Even the chemical/physical properties appear to be unknown, according to the sponsor. The study/data matrix provided in the test plan proposes that each required SIDS element except acute and repeated dose toxicity, genotoxicity in the Ames system and developmental toxicity/teratogenicity will be addressed by new studies.

The robust summary consists of extensive discussions of those few studies that are available and most of these studies appear to be sufficient to address their respective SIDS elements. However, studies of acute toxicity are limited and of questionable quality. Page 7 of the robust summaries indicates that only two rats were used in the acute toxicity study. (Actually in one place it is stated that two animals were used and another place in the same report indicates four were used; this should be clarified.) Nevertheless, the repeated dose toxicity studies at doses ranging up to 4% in the diet of rats indicate bisphenol A dianhydride has little acute toxicity to mammals. Thus, we do not recommend additional studies of acute toxicity. The developmental toxicity/teratogenicity studies used only one dose; however, the fact that no effect was observed in those studies in which either rats or rabbits received a daily oral dose of 1000 mg/kg indicates that bisphenol A dianhydride is not teratogenic.

Note: Page 6 of the robust summaries is blank except for the header. It appears an acute toxicity study is described on page 6, but it is not available for review. The robust summaries should be revised to include

RECEIVED
JUN 30 PM 12:32

this page.

In summary, whereas it is disappointing to see that so little is known regarding an HPV chemical and that General Electric has not provided even the most basic background information, we agree that the present submission should be considered acceptable if all the proposed studies are conducted.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense